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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,091	03/23/2007	Anthony Michael Ging	4398-559	5781

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NIXON & VANDERHYE, PC
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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,091	Applicant(s) GING ET AL.	
	Examiner NIHIR PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Restriction filed on 10/28/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-67 is/are pending in the application.
- 4a) Of the above claim(s) 49-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-46 and 58-61 is/are rejected.
- 7) ☒ Claim(s) 47, 48 and 62-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/20/09; 2/24/09; 2/06/08; 3/23/07; 6/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of **Group I (Species IV; Figs. 31A-31I; claims 40-48 and 58-67)** in the reply filed on October 28th, 2009 is acknowledged. The examiner agrees with the applicant's arguments that claims 40-48 and 58-67 read on the elected species wherein the embodiments of figs 31A-31I includes the claimed usage indicator (claims 40-45), frame connection (claims 45-48) and valve member (claims 58-67)
2. Claims **49-57** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 28th, 2009.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in present application under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy.

Response to Amendment

4. The examiner acknowledges the amendment filed on October 28th, 2009. The amendment comprises cancelling claims 1-39 and withdrawing claims 49-57.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims **40-45** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contains subject matter, specifically “a usage indicator” and “warning signal is in the form of one or more words” is no described in the specification in such a way as to reasonably convey to one skilled on the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on what the examiner regards as a usage indicator since the applicant has not provided any information in the specification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3772

8. Claims **40-42** are rejected under 35 U.S.C. 102(e) as being anticipated by Sprinkle et al. (US 7,621,274).

9. As to **claim 40**, Sprinkle teaches an apparatus that comprises a frame **20** (see **figs. 3 and 4; col. 2 lines 44-51**), a cushion **40** (see **figs. 3 and 4; col. 2 lines 55-62**); and headgear **80** (see **fig. 1; col. 4 lines 45-55**), wherein at least one of the frame, cushion and headgear includes a usage indicator as to condition of the mask assembly (**the frame is made from transparent material and therefore after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material indicating usage of the mask**).

10. As to **claim 41**, Sprinkle teaches an apparatus wherein at least a portion of the frame is made of a material that exhibits stress whitening after repeated movement (**the frame is made from transparent material and therefore after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material indicates stress whitening**).

11. As to **claim 42**, Sprinkle teaches an apparatus wherein the stress whitening takes the form of a warning signal (**the frame is made from transparent material and therefore after using the mask multiple times, the transparent material changes from transparent to a more glassy/frosty material indicates also indicates a warning signal**).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3772

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim **46** is rejected under 35 U.S.C. 102(e) as being anticipated by Gunaratnam et al.

(US 7,185,652).

14. As to **claim 46**, Gunaratnam teaches an apparatus that comprises a frame **11** (see **fig. 3; col. 3 lines 50-55**); a cushion **13** provided to the frame **11** (see **fig. 3; col. 3 lines 50-55**); a cushion clip **14** provided to secure the cushion **13** between the cushion clip **14** and the frame **11** via a first connection (see **fig. 3**); and a swivel elbow **26** (see **fig. 1; col. 2 lines 28-35**) provided to the frame via a second connection, wherein at least one of the first and second connections is provided via a one-way snap which will deform and/or break upon attempt to disassemble.

15. Claims **58-61** are rejected under 35 U.S.C. 102(e) as being anticipated by Dantanarayana et al. (US 2004/0094157).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

16. As to **claim 58**, Dantanarayana teaches an apparatus that comprises a frame **32** (see **fig. 4; paragraph [0071]**); an elbow (see **fig. 44**) provided to the frame and including an inlet

Art Unit: 3772

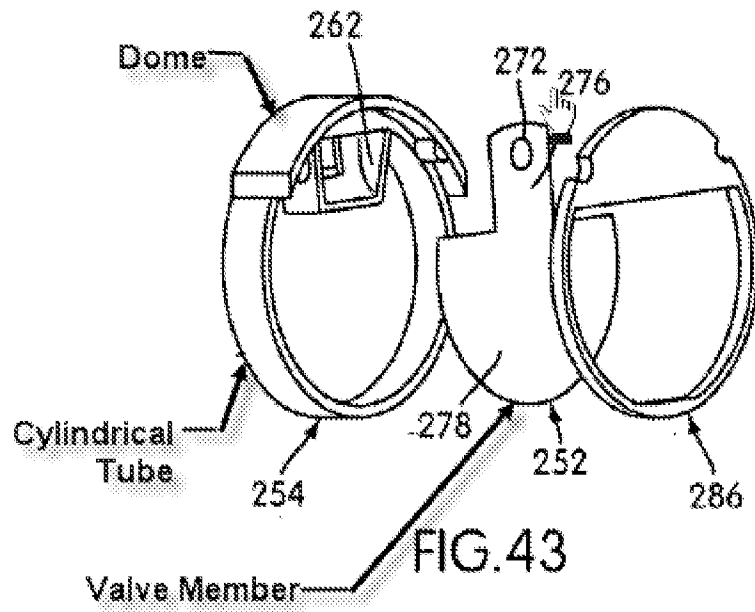
conduit (see fig. 44 below) and a valve member 278 (see fig. 43 below) provided between the frame and the elbow, the valve member being configured to allow breathing of ambient air and to prevent back flow of gas towards the inlet conduit of the elbow in an unpressurized state (see fig. 42; the figure shows arrows in both direction in the exhaust port indicating that that it allows breathing of ambient air and the fact that the valve 278 is closed prevents back flow of gas towards in the inlet conduit).

17. As to claim 59, Dantanarayana teaches an apparatus wherein the elbow includes an internal cylindrical tube 254 (see fig. 43 below) in communication with atmosphere and a dome (see fig. 43 below) that supports the tube, and wherein any back flow is guided through the tube and not the inlet conduit in the unpressurized state.

18. As to claim 60, Dantanarayana teaches an apparatus wherein the elbow includes at least one inlet slot structured to allow ambient air to be channeled between the valve member and the frame for supply to the patient, when operating in the unpressurized state (see fig. 42; the figure shows arrows in both direction in the exhaust port indicating that that it allows breathing of ambient air and the fact that the valve 278 is closed prevents back flow of gas towards in the inlet conduit).

19. As to claim 61, Dantanarayana teaches an apparatus wherein the valve member is structured to separate from the tube during operation in a pressurized state, to thereby allow pressurized gas to enter an aperture of the frame (fig. 40 shows that the valve member is separated from the tube 254 during operation in a pressurized state, allowing gas to enter an aperture of the frame).

Art Unit: 3772



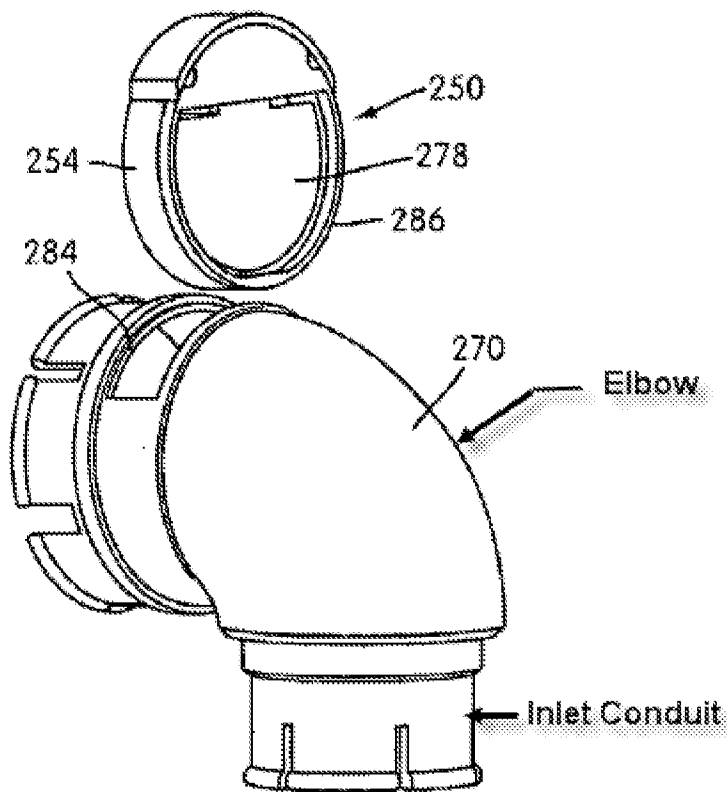


FIG. 44

Specification

20. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Art Unit: 3772

21. The abstract of the disclosure is objected to because the abstract is not on a single paragraph on separate sheet within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

Allowable Subject Matter

22. Claims **47, 48 and 62-67** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a first connection that includes a rod provided to the cushion clip which passes through at least one of the cushion and the frame, wherein the rod includes an enlarged head portion which allows assembly of the cushion clip to the frame, but substantially prevents removal of the cushion clip from the frame; the valve member creating an audible indicator during operation in a pressurized state; and the elbow includes a central tube portion and an inner tube suspended from a dome portion of the elbow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772